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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-62

June 12, 1997

Stefen J. Gitterman, President
Health Care Respiratory, Inc.
7000 S.W. 22nd Court, Suite 153
Davie, Florida 33317

Dear Mr. Gitterman:

Inspection of your medical gas filling operation on May 29, 1997, by FDA investigator Philippe L. Noisin, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to test each component lot of bulk compressed oxygen to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. Refilled cylinders of compressed medical Oxygen USP are not adequately tested for purity prior to release for distribution. The [redacted] Oxygen Analyzer used by your firm is not an acceptable test device for oxygen purity in that the accuracy of the device is not equivalent to the USP test accuracy of ± 0.1%.

During the inspection, the filling of a cylinder (serial number BC9230) with medical oxygen was observed. You failed to perform several significant steps in the filling operation, such as visual inspection of the cylinder, use of a vacuum pump to evacuate the cylinder, perform an odor test, leak test, pressure test, and obtain a temperature reading of the cylinder. You did not calibrate the [redacted] Oxygen Analyzer used to test the filled cylinder and subsequently obtained a 102.4% purity reading. You recorded a 99% oxygen purity test result on the oxygen analysis record even though the test result obtained was 102.4%. In addition, the investigator

documented three cylinders (serial numbers D155344, E218512, and E296647) filled with medical oxygen that have not been hydrostatic tested since February 1985, May 1987, and October 1988, respectively.

Written procedures are not established for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess. For example, no written procedures are established for cylinder filling and testing, calibration and maintenance of equipment, labeling, handling of complaints, employee training, or supervision.

Batch production and control records have not been established and no documentation is available to show that each significant step in the manufacturing operation was completed, such as all required pre and post fill cylinder inspections and testing. Records documenting calibration and maintenance of equipment are not maintained, and there is no documentation that you have received adequate CGMP training.

Review of labeling used on cylinders of compressed medical oxygen filled by your firm also reveals the products to be misbranded within the meaning of Sections 502(a), 502(b)(1) and (2), 502(e)(1)(A)(i), 502(f)(1) and (2), and 503(b)(4) of the Act. One cylinder (serial number E726826) filled with medical oxygen failed to bear a label. Some labels bear the unqualified name and place of business of other firms, such as Puritan Bennett, John Bunn Company, and Mountain Medical Equipment, and fail to bear the place of business of your firm. Except as provided in 21 CFR 201.1(h), no person other than the manufacturer, packer, or distributor may be identified on the label of a drug product. As the refiller, your firm is considered to be the manufacturer. Therefore, only your firm's name and place of business should appear on the label. If a distributor is named on the label, the name must be qualified in accordance with 21 CFR 201.1(h)(5). Some labels also fail to bear an accurate statement of the quantity of contents, the established name of the product as it appears in the official compendium (Oxygen USP produced by the air-liquefaction process), and the statement "Caution: Federal law prohibits dispensing without prescription". In addition, some cylinders bear lot numbers and out-dated expiration dates that were not assighed by your firm.

With respect to the above referenced 502(b)(2) violation, the contents of cylinders may be expressed in terms of the available volume of Oxygen USP in liters at 70° F (21.1° C) and one (1) atmosphere.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As president and owner, it is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

Douglas D. Tolen
Director, Florida District